Remarks/Arguments

Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 are pending. Claims 1-49, 53, 55, 76, 78, 96 and 105-107 remain canceled. No claims have been amended. No new matter has been added.

103 Rejections

Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 remain rejected under 35 U.S.C. §103(a) as being unpatentable over WO 98/07414 ("the '414 publication") in view of US Patent No. 5,976,577 ("Green") or US Patent No. 6,475,510 ("Venkatesh"). The Examiner alleged that the '414 publication discloses the same process of preparing rapidly dispersing oral dosage forms of hydrophobic compounds as the instant application but does not disclose the additional step of adding at least two rapidly dispersible matrix-forming releasing agents. The Examiner further alleged that both Green and Venkatesh disclose fast dispersing solid dosage forms of various drugs. The Examiner states that as the inventive entity of the '414 publication is different from the inventive entity of the instant application, thus the '414 publication can be considered prior art. Applicants disagree.

Applicants submit that a reference "by others" under 102(a) refers to any entity which is different from the inventive entity and the entity need only differ by one person to be "by others." (*See*, MPEP 2132 III). However, if the Applicants' disclosure is his own work, dated within one year before the application filing date, that disclosure cannot be used to establish a *prime facie* case under 35 U.S.C. 102(a). (*See*, MPEP 2132.01). Additionally, when the Applicant is one of the co-authors of the publication being cited against his own application, the publication may be removed as a reference by filing a Declaration establishing that the relevant portions of the reference is the Applicants' own work. (*See*, MPEP 2132.01).

Applicants re-submit that Indu Parikh, in the Declaration filed on December 29, 2008 (courtesy copy attached), establishes that what he invented in the '414 publication included a process of preparing rapidly dispersing oral dosage forms of hydrophobic compounds wherein the particles are coated with at least two surfactants; wherein one of the surfactants was a phospholipid (surface modifying agent). The average particle sizes of the hydrophobic

compound were less than 10 microns. The composition contained other materials such as cellulose and mannitol. The process of preparation involved mixing of the components (water insoluble active agent and the surface modifying agents) in an aqueous medium, sonicating it and lyophilizing the composition to form particles. The lyophilized powders could be converted into granules or tablets with the addition of binders and other excipients. Further, Indu Parikh, in the Declaration filed December 29, 2008, asserts that the other inventors of the '414 publication did not work on the portions of the '414 publication cited by the Examiner.

Applicants also submit under 37 CFR § 1.132 a second Declaration by Indu Parikh, who is a co-author of the '414 publication cited in the instant 103(a) rejections. In the second Declaration, Indu Parikh establishes that co-author Ulagaraj Selvaraj's contributions include selecting a surfactant(s) that provide volume-weighted mean particle size values of the water-insoluble compound at least 50% smaller than particles produced without the presence of the surfactant using the same energy input and not the subject matter relied upon by the Examiner in this rejection.

Thus, the '414 publication, insofar as its teachings relate to the subject matter of the instant claims, is not a publication by another, and thus cannot be prior art under 35 U.S.C. § 102(a) or under 35 U.S.C. § 103(a).

Withdrawal of the rejection is thus respectfully requested.

Double Patenting

Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 remain rejected under obviousness-type double patenting over claims 1-11 of U.S. Patent No. 5,922,355 ("Parikh I") in combination with either Green or Venkatesh.

Applicants re-submit that claims 1-11 of Parikh I do not teach or suggest the limitations of claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 in light of the general knowledge of one of ordinary skill in the art and that there has not been sufficient explanation pertaining to why despite these the instant claims are obvious over claims 1-11 of Parikh I in combination with either Green or Venkatesh.

Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.[1]

Pending claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 recite a suspension, where upon reconstitution in an aqueous environment, does not have more than about 20% by weight of particle aggregation or agglomeration compared with the amount of aggregation or agglomeration of particles comprising a pre-dried suspension.

Claims 1-11 of Parikh I do not teach or suggest a process for the preparation of a rapidly disintegrating solid dosage form wherein upon reconstitution in an aqueous environment, the suspension has no more than about 20% by weight of particle aggregation or agglomeration compared with the amount of aggregation or agglomeration of particles comprising a pre-dried suspension. The size of the microparticle affects the bioavailability of the active ingredient. Specifically, smaller microparticles, whose particle size is more difficult to maintain upon reconstitution, increase the bioavailability of the active ingredient. The key feature of the invention is to maintain particle size, which is initially about 1 micron, and prevent any particle size growth and irreversible aggregation and/or agglomeration upon reconstitution. The presence of any small (under 20%) portion of aggregates, can be dispersed by low levels of energy in a short period of time. Such a limitation or benefit is not taught or suggested by the claims of Parikh I. Rather, the claims of Parikh I teach that during the preparation of the microparticles, energy is applied to produce a volume-weighted mean particle size that is reduced by 50%. (*See*, Parikh I at claim 1 and claim 2). Neither Green nor Venkatesh cure these deficiencies as neither of the claim sets teach or suggest recite requirements of no more than 20% by weight of particle aggregation or agglomeration compared with the amount of aggregation or agglomeration of particles comprising a pre-dried suspension.

[1] MPEP § 2141

Applicants re-submit that claims 1-11 of Parikh I in combination with Green or Venkatesh do not teach or suggest all of the limitations of pending claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 and respectfully request that this rejection be withdrawn.

Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 remain provisionally rejected under the obviousness-type double patenting over claims 1, 2, 4-25, 45-47, 52-53, 55-56, 65 and 101-119 of co-pending application U.S. Serial No. 10/260,788 in combination with either Green or Venkatesh. Applicants note that this is a provisional double patenting rejection for which the M.P.E.P. at § 1504.06 Double Patenting provides as follows:

> If a provisional double patenting rejection (of any type) is the only rejection remaining in two conflicting applications, the examiner should withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the provisional double patenting rejection in the other application which rejection will be converted into a double patenting rejection when the first application issues as a patent. If more than two applications conflict with each other and one is allowed, the remaining applications should be cross rejected against the others as well as the allowed application. For this type of rejection to be appropriate, there must be either at least one inventor in common, or a common assignee. If the claims in copending design applications or a design patent and design applications have a common assignee but different inventive entities, rejections under 35 U.S.C. 102(e), (f) and (g)/103(a) must be considered in addition to the double patenting rejection. See MPEP Section 804, Section 2136, Section 2137 and Section 2138.

Accordingly, Applicant request withdrawal of this provisional rejection should the Examiner find the present claims allowable in view of the above amendments and/or arguments.

On the basis of the foregoing amendment and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. Should any questions or issues arise concerning this application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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